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QUALITY FOR LIFE

K101524

510(k) SUMMARY of SAFETY and EFFECTIVENESS

SEP 29 2010

A. General Information

1. Submitter's Name.:	OTTO BOCK Health Care, LP
2. Address:	Two Carlson Parkway North, Suite 100 Minneapolis, Minnesota USA 55447-4467
3. Telephone:	763-253-5610
4. Contact Person:	William Kabitz, Quality Assurance Manager
5. Date Prepared:	December 1st, 2009
6. Registration Number:	2182293

B. Device

1. Name:	C2000 Powered Wheelchair
2. Trade Name:	C2000 Outdoor Wheelchair
3 .Common Name:	Powered Wheelchair
4. Classification Name:	Wheelchair, Powered
5. Product Code:	ITI
6. Class:	II
7. Regulation Number:	21 CFR 890.3860

C. Identification of Legally Marketed Predicate Device

1. Name:	C1000 Powered Wheelchair
2. Manufacture:	Otto Bock HealthCare, Mobility Solutions
3. K Number:	K041211
4. Date Cleared:	October 1, 2004

D. Description of the Device

The C2000 power wheelchair is suitable for indoor and outdoor use. It is compactly designed and easy to maneuver for use indoors. Two 12 V batteries power its high-performance drive system, which allows the C2000, along with spring mounted drive wheels, to overcome obstacles (category C of EN 12184) and to ensure safe operation.

The C2000 power wheelchair is controlled by an enAble50 wheelchair control system. It includes a control panel to enter driving commands and display the current status as well as a controller that controls the drive

motors and other electrical functions based on the input data. Data transmission is realized via a bus system.

The enAble50 can be programmed to the personal requirements of the user; e. g. the speed, acceleration and deceleration values can all be personalized.

E. Features

The special features of the C2000 power wheelchair include:

- Reversible seat positioning using a parts kit, in order to change between front-wheel drive and rear-wheel drive.
- Chain steering.
- Easy servicing due to clear accessibility of all component groups
- Customization with options and custom fabrication using modular components.

F. Intended Use Statement

The C2000 power wheelchair is intended exclusively for individual indoor and outdoor self-transportation by persons with walking impediments or walking inabilities.

G. Field of Application

The C2000 is suitable for individuals who are unable to walk or have severe walking impediments due to:

- Palsies/Paralyses
- Loss of limbs
- Defective and/or deformed limbs
- Joint contractures
- Joint defects
- Other diseases

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H. Technological Characteristics Summary

The C2000 Powered Wheelchair is substantially equivalent to the C1000 Powered Wheelchair, cleared on October 1, 2004.

Each wheelchair is a powered wheelchair for the active user, with a rigid frame and similar characteristics.

The safety of the C2000 has been confirmed by CE certification. The C2000 was tested by TÜV in Hanover Germany to the following standards:

DIN EN 12184:1999

IEC 60601-1-4

ISO 7176-1:1999

ISO 7176-3:2003

ISO 7176-5:2008

ISO 7176-7:1998

ISO 7176-8:1998

ISO 7176-10:2008

ISO 7176-11:1992

ISO 7176-13:1989

ISO 7176-14:2008

ISO 7176-15:1996

ISO 7176-16:1997

ISO 7176-21:2003

ISO 7176-21:2007

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OTTO BOCK Health Care, LP
% Mr. William Kabitz
Quality Assurance Manager
Two Carlson Parkway North, Suite 100
Minneapolis, Minnesota 55447

Re: K101524
Trade/Device Name: C2000 Powered Wheelchair
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered wheelchair
Regulatory Class: II
Product Code: ITI
Dated: August 11, 2010
Received: August 13, 2010

SEP 29 2010

Dear Mr. Kabitz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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APPENDIX J

SEP 29 2010

Indications For Use Form

510(k) Number (if known): To be determined

Device Name: C2000 Powered Wheelchair

Indications for Use:

Provide mobility to persons physically challenged and limited to sitting positions due to:

- Palsies/Paralyses
- Loss of limbs
- Defective and/or deformed limbs
- Joint contractures
- Joint defects
- Other diseases

Prescription Use ____ AND/OR Over-The-Counter Use __X__
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE
CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101524